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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,684	01/10/2002	Eric M. Nelson	P-LX 4948	2349

23601 7590 04/23/2003

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EXAMINER

DAVIS, DEBORAH A

ART UNIT	PAPER NUMBER
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1641

7

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/914,684

Applicant(s)

NELSON ET AL.

Examiner

Deborah A Davis

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The Patent documents submitted on 10/11/01 included US patents and a EP patent for consideration but without an official cover letter listing the patent numbers for consideration or statement of relevance. Accordingly, the following US Patents have been considered: 5,597,532; 5,470,752, 5,695,949, 6,024,919 and EP 0215419.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Nelson et al (USP#6,024,919).

Nelson et al anticipates the instant claims by teaching a method and apparatus for controlling the absorption of a liquid sample. Nelson et al provides a method and apparatus of manufacture for receiving a liquid sample, such as blood and other body fluids (column 2, lines 47-50) where a first portion of the polymer layer overlies a solid surface and a second portion of the polymer layer overlies a window (see abstract). Sonic treatment of the polymer layer will selectively reduce the void volume of a sintered polymer layer such as a porous high-density polyethylene (see abstract). The apparatus contains a reaction layer comprising reagents that can react with specific analytes in a liquid sample (column 2, lines 61-62). The apparatus has an air gap (column 6, lines 45-49) comprising a space or hole between two separate solids (see Figure 2, 4b) and a reflectance monitor (translucent window) for view color reactions and changes in the reaction layer (column 9, lines 58-65). The apparatus also comprise of at least one sidewall and wherein the layers, walls and window define an air gap (see abstract and Figure 2).

4. Claims 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Blatt et al (EP # 0215419).

Blatt et al anticipates the instant claims by teaching a method and apparatus for controlling the absorption of a liquid sample through an absorbent layer. Blatt et al provides for a flow metering capillary device for controlled fluid flow comprising several embodiments that include opaque or black cover sheet (translucent window), a reagent layer, walls surrounding the inner surface of the sample chamber (Figures 1-3, label 8),

Art Unit: 1641

a window and an air relief port (air gap) (page 15, lines 1-30). The apparatus has a non-fogging window such that it enables one to monitor the filling of the sample chamber by use of a cover sheet and then observing the appearance through a release port. Superior temperature control characteristics are achieved because virtually no fluid sample remains exposed to the atmosphere, which means that the invention also completely eliminates evaporative cooling effects (page 30, lines 26-31 and page 31, lines 1-5).

5. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Burd et al (USP#5,939,331).

Burd et al anticipates the instant claims by teaching a method and device for detecting the presence or amount of an analyte in a whole blood sample.(see abstract). Burd et al provides a method of controlling fluid flow by utilizing a lateral flow device that comprise of an absorbent zone (absorbent layer), a side wall and a translucent window. The liquid is applied on the opposite side of the slits (air gap) that flows through to the absorbent zone (see abstract, label 39). A top cover (abstract, label 17) is constructed and adapted to fit snugly with the bottom cover (abstract, label 11) which is a feature that defines preventing the release of air from the slits (air gap).

### ***Conclusion***

6. No claims are allowed.

Art Unit: 1641

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

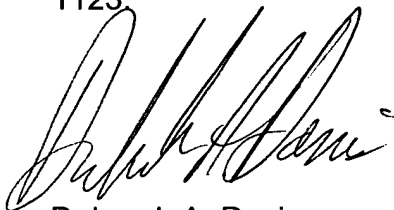
A. May et al discloses a test device for detecting an analyte in a liquid sample (USP#5,275,785).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

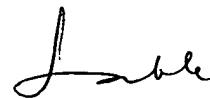
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1123



Deborah A. Davis  
CM1, 7D16  
April 10, 2003



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
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04/21/03